

SPL Process ER/DL Meeting

Meeting Minutes

Jul 27, 2016

Chair of today's meeting: Pat Cowall

Teleconference information:

USA Toll-Free: 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. CBER approval letters – request for SPL to contain both carton and container label (Ben Harpster)
Text from approval letter:
Please submit final printed labels for each of the above listed products you are authorized to manufacture at this location showing the new corporate name and license number.
Please submit the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format and include the carton and container labels.

Meeting discussion:

- Warren Sunshine (Pfizer): They include every piece of artwork for ALL CBER submissions. In addition to the SPL, they also have to submit a "Time of first use submissions." i.e. These labels are all in use today....day of first use. Word, pdf, all artwork, and SPL. They continuously update.
- The text above corresponds to what they want in the "time of first use submission." Their record is 35 labels in one SPL.
 - o First use submission: does this include only the first use...or all? Full complement of all labeling in use at that time.
- Smitha (Amgen) also includes both ALL current carton and container labels in their SPL.....not a representative sample of labels.
- Related question – do you include the complete piece of artwork....or just the principle display panel?
 - o Pfizer: whole label
 - o Amgen: just the principle display panel.
 - o Lilly: usually whole label, but if it isn't readable, then we may only use the principle display panel.
 - o SPL on Daily Med has lots of variability in whether just front panel or all panels.
 - o Astra Zeneca: just front display panel
 - o Baxter: Only company on the call for which FDA has requested that they submit all panels.

2. ACE system and imports (Marcia Howard and Ben Harpster)

Are people having problems getting products cleared through Customs? Several companies are experiencing problems and delays in getting shipments cleared....many more problems than the previous months. See new proposed rule:

<https://www.gpo.gov/fdsys/pkg/FR-2016-07-01/pdf/2016-15684.pdf> FDA Submission of Food and Drug Administration Import Data in the Automated Commercial Environment; Comments due to FDA by **August 30, 2016**.

Meeting discussion:

- Lilly: We planned for the ACE system – ie coordinating with the SPL group. FDA release of our entries has been the usual 3 business days – so we haven't noticed a delay so far either.
 - We provide data to our customs broker in the form of a template for each imported drug product or API with an individual NDC# when intended for commercial use. We also do this for any FDA regulated products intended for research/in-vitro testing only or for investigational use (IND). We did this to avoid having data entered inconsistently or incorrectly as appears to be happening to some importers according to the message below.
 - Each Lilly Manufacturing site has templates to include with their shipments to the U.S. as well.
- ACE went live on June 15, 2016.
- DUNS lookup actually is on the ACE web page.
- Dragan -- Abbott: no difference either.
- Dragan -- Abbott: FDA went away with the import for export allowance. There are still listing requirements for that. You don't do this the same way – use drug for further processing.

3. SPL REMS update (Pat, Terry , et al.)

- REMS background:
 - o Requested/driven by NCPDP
 - o Downstream users will be alerted as they are prescribing / dispensing products which have REMS – systems would be able to extract content from the structured data and present it to the HCP.
- FDA has completed the pilot.
 - o Good participation from industry
 - o FDA learned a lot about process and data
- Next steps for FDA:
 - o Finalize process and data
 - o Industry rollout/webinar: FDA webinar
 - o Publish draft guidance
 - o Two year comment → Final Guidance
- Implementation:
 - o Will be ready to start accepting SPL REMS in several months.
 - o Mandatory after final guidance is published—optimistically in 2019.
 - o

- FDA us hoping industry will submit REMS SPL soon. In fact, FDA will be providing help for a limited time during the initial stages of the rollout.
- SPL Team follow-ups:
 - SPL Process ER/DL team: will collect questions after the FDA webinar – will potentially invite Adam Kroetsch and Aaron Sherman to our meeting to discuss
 - SPL Tech team: also planning meeting to cover the techy items – mechanics of the SPL.

Meeting discussion:

- Question: How will the data be used downstream? (Bill Friggle)
 - Need to engage with NCPDP
- Question: How can we link this work back to industry to get better REMS management (Bill Friggle)
 - Better communication with HCPs
 - How can industry receive feedback on how REMS is working
- Future discussions will be coming: Do we need a REMS discussion group – with those people that have REMS?
 - Keith Fisher (Point of Care) – would be willing to help lead these discussions. He will contact Tom Bizarro (First Data Bank) and see if they can work together to help lead this discussion.
 - Bill Friggle will help provide an industry perspective.
 - Pat will ask Ed Millikan from ASHP to share his experiences with problems implementing REMS.
 - We will plan an SPL Process ER/DL meeting following the FDA REMS SPL kickoff – questions resulting from the FDA meeting, and these questions, etc.
 - If you are interesting in participating, please let us know

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Agenda for August 10th meeting:

1. SPL topics (Lonnie Smith)
 - Basis of strength
 - Package level start / end dates in the NSDE file

2. Question on New document type: Drug for further processing (Lonnie Smith)

Please clarify the process for implementing the new “Drug For Further Processing” document type and any timing for the implementation of validation check changes.

- how long will we be able to submit a listing with a document type of “bulk ingredient” (53409-9) and a marketing category of “drug for further processing” (C94795)?
- how long will we be allowed to change the document type of a file (setid) from “bulk ingredient” (53409-9) to the new document type of “drug for further processing” (C78744-0)?
- When will these validation rules be implemented?

4.1.1.2 If a document with the same set id has been previously submitted, then it is of the same type, except if the previous document type was Bulk Ingredient (53409-9) and the present document type is Drug for Further Processing (78744-0).

3.2.9.5 If the document type is 53409-9 (bulk ingredient) or Drug for Further Processing (78744-0), then the marketing category is C73626 (bulk ingredient), C94795 (drug for further processing), C96793 (bulk ingredient for human prescription compounding), C98252 (bulk ingredient for animal drug compounding), or C73590 (export only).

3. Bulk" listings (Maricarmen Dilone-Raposo)

Meeting discussion:

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4. NDC codes for commercial versus samples (Smitha Mathew)

Do companies issue separate NDC codes on carton and container for

- a. Commercial vs
- b. Professional samples/Not for Sale sample

Meeting discussion:

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5. Does anyone have an example of a kit (drug cartridge and device injector packaged together in a carton), Smitha Mathew
- if the device injector does not contain drug, do you still assign a NDC code to it?

Meeting discussion:

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6. More to come

Meeting discussion:

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Ongoing followup items:

Dual FEI numbers – any updates?

- In 2008, companies were assigned multiple FEI numbers – especially for foreign sites. I.e. a site had 2 FEI numbers, and FDA was requesting changing to the newer number, potentially different from what was in registrations.
- Who should you contact to correct this?
Information from January meeting minutes:
 - eDRLS office and then forwarded to the ORA office.
 - ORA: Irma Rivera: irivera@ora.fda.gov
 - ORA: Susan Laska: Susan.Laska@fda.hhs.gov
- Any other updates on this?

Coming Event: SPL Jamboree 2016: Tuesday Sept 27, 2016